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MEMORANDUM

TO: Interested Parties

FROM: Robert Walker, Director  
Radiation Control Program

DATE: July 21, 2005

SUBJECT: Proposed Amendments to the Massachusetts Regulations for the Control  
of Radiation (MRCR) (105 CMR 120.000 et seq.)

The existing set of comprehensive regulations pertaining to the control and use of radioactive material and radiation in the Commonwealth was first drafted by the Radiation Control Program (the "Program") in March of 1994, and approved by the Public Health Council on February 24, 1995. These regulations were last amended on July 9, 1999. Promulgating these comprehensive regulations was a necessary precursor for Massachusetts to achieve Agreement State Status with the Nuclear Regulatory Commission (NRC). An Agreement State is one to which the NRC legally transfers authority to regulate possession and use of most types of radioactive materials based on the state's agreement to maintain a comprehensive Radiation Control Program and to promulgate regulations that are compatible with, and at least as restrictive as, the NRC regulations. Periodic revisions of the regulations are necessary to adopt new compatibility requirements imposed by the NRC.

The primary purpose for the current proposed revisions is to adopt in 105 CMR 120.500 new requirements imposed by the NRC in its regulations regarding the medical use of byproduct material (10 CFR Part 35). The overall goals of the revisions are to implement NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and to structure the regulations to be more risk-informed and more performance-based.

Because of the major changes made to 10 CFR Part 35, the Agency has revised 105 CMR 120.500 in its entirety. The proposed new 105 CMR 120.500 includes the following changes:

2. Deletion of the requirement that a licensee submit all required written procedures for review by the Agency.
3. Addition of a rule that requires the licensee to report a dose equivalent greater than 50 millisievert (5 rem) to an embryo/fetus or nursing infant which is the result of administration of radioactive material or radiation from radioactive material to a pregnant individual or nursing mother.
4. Addition of rules for high-dose-rate, pulsed-dose-rate and low-dose-rate remote afterloaders, and gamma stereotactic radiosurgery units.
5. Deletion of the requirement that all medical institutions must have a Radiation Safety Committee.
6. More stringent training and experience requirements for authorized users of unsealed radioactive material for therapy (with the exception of oral sodium I-131 users).
7. Less restrictive training and experience requirements for authorized users of oral sodium I-131 in activities less than 33 mCi.
8. Addition of rules for the regulation of new medical uses of radioactive material (See 105 CMR 120.589).
9. Inclusion of the requirement that the preceptor authorized user must submit written certification that the individual has achieved a level of competency sufficient to independently function as an authorized user for the medical uses requested.
10. Less reiteration of rules that are also found in other parts (such as 105 CMR 120.200).

Other sections of the regulations have been revised for compatibility and uniformity. These revisions are summarized as follows:

105 CMR 120.001: General Provisions

120.005: Additions and deletions for clarification in the Definitions Section, in particular the Radiation Protection Requirements

120.016(K): New Section - Enforcement Action for Deliberate Misconduct

105 CMR 120.100: Licensing of Radioactive Materials

120.122(D): New controls on Generally Licensed (GL) Devices.  
120.128(D): New requirements for the distribution of GL Devices.  
120.125(C): Adjustments in Financial Surety requirements.  
120.132(E): Clarification of Decommissioning Funding Requirements  
120.190(C): Explicit recognition of areas in Massachusetts under exclusive Federal jurisdiction.

105 CMR 120.200: Standards for Protection Against Radiation

120.200: Minor Corrections, Clarifying Changes, and a Minor Policy Change  
120.203: Radiation Protection Requirements: Amended Definitions and Criteria  
120.233: Respiratory Protection and Controls to Restrict Internal Exposures  
120.244-249 Radiological Criteria for License Termination  
120.256: Low-Level Waste Shipment Manifest Information and Reporting

105 CMR 120.300: Radiation Safety Requirements for Industrial Radiographic Operations

Revision of the Industrial Radiographer Certification requirements.

105 CMR 120.400: X-Rays in the Healing Arts

120.403: General requirements to strengthen quality control.  
120.405(C): Fluoroscopic x-ray systems - Exposure rate limits.

105 CMR 120.430: Therapeutic Radiation Machines

Minor revisions to align with revisions made to 120.500.

105 CMR 120.000: Generally

Minor edits and corrections have been made throughout the regulations to improve readability and clarify existing standards.

A draft containing all of the above changes is available for your review and comments at the Agency's website (go to [mass.gov/dph/rcp](http://mass.gov/dph/rcp), then on the left side, click "Regulations & Statutes" and go to "Draft Changes to Regulations for Comment") for your review and comments. All deletions to the regulations are shown as strikeouts(~~strikeouts~~) and all additions are redlined(redlined). A public hearing has been scheduled for August 31, 2005, at 10:00am in the Bowditch Public Health Council Room at the Massachusetts Department of Public Health offices at 250 Washington Street in Boston.

The comment period itself will close at 5:00pm on September 7, 2005. Copies of comments can be submitted directly to the Radiation Control Program at 90 Washington Street, Dorchester, MA 02121, but must arrive no later than the September 7, 2005, 5:00pm deadline.

Oral comments may be made at the Public Hearing, although it is not necessary to do so. Generally, the oral comments, if they are made, are a summary and are accompanied by written comments if they are extensive.

We appreciate your comments and attention to these draft proposed regulations, and if you have any questions, please call my office at 617-427-2944.